(a) a polynucleotide sequence encoding the same mature polypeptide encoded by the human cDNA in ATCC Deposit No. 97186; and

(b) the polynucleotide sequence complement of (a).

39. (Amended) The isolated polynucleotide of claim 37, wherein said polynucleotide sequence comprises DNA identical to the coding portion of the human cDNA in ATCC Deposit No. 97186 which encodes a mature polypeptide.

41. (Amended) A process for producing a polypeptide comprising:

expressing from a recombinant cell transformed to contain [containing] the polynucleotide of claim 34 the polypeptide encoded by said polynucleotide, and isolating said polypeptide.

Remarks

Claims 21-41 are pending and amendments have been made to the respective claims for which the Examiner requested clarity. Such changes have been made without prejudice and applicant believe that all of the Examiner's concern have been addressed in the manner generally suggested by the Examiner.

The Title will be amended at such time as the case is indicated as allowable.

A replacement Sequence Listing has been provided which provides new SEQ ID NOS:9-28, which correspond to the sequence

segments of Figure 3. Further, the Sequence Rules are fully complied with since the one-letter amino acid codes of Figure 3 are cross-referenced with SEQ ID NOS that have three-letter code sequences.

Accordingly, any objections to this regard are believed to be fully overcome and should be withdrawn.

Although applicant believes that the present application fully complies with the deposit requirements, appended hereto is the deposit receipt for ATCC 97186. The deposit receipt cross-references client docket number "PF201" with ATCC 97186, which the undersigned certifies by the signature below corresponds to the present application and docket number 325800-458. Thus, the present application which refers to a deposit is correct in doing so and the particular deposit referred to on page 7 of the specification is ATCC 97186. Therefore, this ground of rejection is overcome and should be withdrawn.

As pointed out above the formality rejections with regard to clarity are believed to all be adequately addressed. Thus, the only issue remaining is enablement for the present claims under 35 U.S.C. §112, first paragraph.

Applicant notes with appreciation that the claims are free of the prior art.

Therefore, in view of the obviated formality rejections the only issues remaining are with regard to the utility of the polynucleotide having a sequence according to SEQ ID NO:1 and for polynucleotides having at least 95% sequence identity to a sequence which encodes the polypeptide of SEQ ID NO:2 (and utility of the polypeptide of SEQ ID NO:2 as well) or complements thereof, or to a process claim which utilizes such polynucleotides as starting materials to make polypeptides encoded thereby. Reconsideration of this ground of rejection is respectfully requested in view of the following remarks and the above amendment.

Since the claims are drawn to two types, namely the polynucleotide claims and a process for utilizing such polynucleotides for the production of polypeptides, the utility rejection with regard to polynucleotides will be addressed separately from the rejection with regard to polypeptides.

The best point of understanding to have in order to be on the same grounds of reasoning and reach a common understanding of the law and facts of this case is to first review the requirements of 35 U.S.C. §112, first paragraph.

The requirements under 35 U.S.C. §112, first paragraph, for enablement are only two: (1) how to make the claimed invention and (2) how to use the claimed invention.

Prior to beginning such analysis we can note the subject matter indicated as allowable by the Examiner. Such subject matter is not subject to the enablement rejection. Regardless of any other biological use, the specification at pages 29-32 supports and enables the following unique and novel polynucleotides as probes for chromosome mapping:

> an isolated polynucleotide selected from the group consisting of:
>
> (a) a polynucleotide encoding a polypeptide comprising the amino acid sequence from amino acid 2 to 541 of SEQ ID NO:2 or encoding the polypeptide encoded by the human cDNA in ATCC Deposit No. 97186, and
>
> (b) the complement of (a).

Please note that the polynucleotides which are complements (b) are useful for isolating the polynucleotides of (a). In main claims such complementary polynucleotide sequences can be either a RNA or a DNA sequence (not just a mRNA sequence that is naturally occurring).

With regard to polypeptide (SEQ ID NO:2) encoded by the polynucleotide sequences of (a) that is clearly allowable in view of the utility described on pages 29-30 of the specification (directed to chromosome identification and isolation), such polypeptide and a method for making same are also useful. The G-protein receptor use is set forth in the specification, but the polypeptide of SEQ ID NO:2 is also useful as a marker for detecting the successful insertion of a construct polynucleotide according to

SEQ ID NO:2 into a recombinant host cell. Such use is elucidated by the description on pages 28-31 of the specification with regard to the generation of antibodies to the polypeptides or fragments thereof, particularly monoclonal antibodies. Such antibodies are useful for detecting and quantify amounts of the polypeptide in a sample. Therefore, in view of the state of the art and the description of the specification of how to generate recombinant hosts which comprise the polynucleotide according to SEQ ID NO:1, once a monoclonal antibody has been generated that is specific for the polypeptide, as disclosed on pages 29-30 of the specification, such antibodies can be utilized to isolate the polypeptide when it is expressed. Thus, the polypeptide when isolated from a recombinant cell would indicate by its presence the successful insertion of the polynucleotide according to SEQ ID NO:1. See pages 21-30 of the specification for a discussion of the generation of recombinant host cells. Accordingly, the polypeptide is useful in the generation of such monoclonal antibodies for example and as a marker for successful insertion of the polynucleotide into a host cell.

In addition the polypeptides which are encoded by the complements (b), while not having the biological activity of the polypeptide encoded by (a) sequences are still taught as useful by the present specification. At pages 27 to 31 of the specification such polypeptides are indicated as useful for making antibodies such as monoclonal antibodies for detecting the presence of themselves (polypeptides) in a sample. Thus, one of ordinary skill

in the art, in view of the state of the art would appreciate that such antibodies would be useful in the production of host cells comprising the complementary polynucleotides according (b), for example. Please note that the process claims are limited to production from host cells comprising a polynucleotide sequence which is not the complement, but such polypeptide production would be regarded as an equivalent process within the scope of the present invention.

As indicated above, such antibodies to the polypeptide may be utilized to determine if a construct comprising the polynucleotide complement has been successfully inserted into a host cell. The host cell having the insert can then be cultivated and a polynucleotide complement probe utilized to isolate the multiplied construct polynucleotide from the host cells after destruction of the cell walls of the host cells, for example.

Therefore, independent of additional biological activity for the polypeptide encoded by such complements, such polypeptide is useful for making useful monoclonal antibodies and therefore a process for making such polypeptides has patentable utility.

Further, redundant sequences encode a mature polypeptide having a sequence as set forth in SEQ ID NO:2 and such polynucleotides are useful to manufacture the useful polypeptide according to SEQ ID NO:2. Likewise the complements to the redundant sequences are useful for isolating the redundant

polynucleotides. Thus, how much such redundant sequences might vary from one another and whether they will hybridize to one another are irrelevant with respect to utility.

Therefore, clearly, the claims to the polynucleotide according to SEQ ID NO:1 or the redundant polynucleotides encoding the polypeptide sequence according to SEQ ID NO:2 as well as the complements to such polynucleotides are useful as probes to isolate their respective useful complement. The polypeptide according to SEQ ID NO:2 is useful for producing monoclonal antibodies as set forth above. Further, without regard to the presence or absence of biological activity for the polypeptides encoded by the complementary sequences discussed above, such polypeptides are useful to produce useful monoclonal antibodies for the reasons set forth above.

Accordingly, the 35 U.S.C. §112, rejection with regard to such species is deemed moot.

Therefore, the only issue remaining relates to polynucleotides comprising a polynucleotide sequence which is at least 95% identical to a respective useful polynucleotide (to the polynucleotide sequence according to SEQ ID NO:1 or to a redundant polynucleotide sequence encoding the same polypeptide as encoded by the polynucleotide of SEQ ID NO:1, or to the complement of either of SEQ ID NO:1 or a redundant sequence).

The specification describes such polynucleotides having at least 95% identity with the polynucleotide sequence according to SEQ ID NO:1 and the polynucleotide sequence of the deposited cDNA according to the invention, or at least 95% identity to a redundant sequence encoding the same polypeptide as that encoded by SEQ ID NO:1 or the deposited cDNA. In particular pages 5-18 of the specification (and recombinant methods on pages 23-28), for example, describe such polynucleotides and how they may be obtained. Accordingly, one of ordinary skill is taught how to make polynucleotides which are at least 95% identical to the polynucleotides according to the present invention.

Moreover, the state of the art is such that a simple computer program loaded with the polypeptide sequence information of SEQ ID NO:2 can easily generate the redundant sequences and their complements. Each of such polynucleotide sequences ("basic polynucleotide sequences") which encode the polypeptide according to SEQ ID NO:2 or their complements, respectively, can be readily randomly varied by the same computer program to result in a respective polynucleotide having at least 95% identity to the respective polynucleotide sequence. Such computer usage is totally routine, within the skill in the art and often utilized in the art. Further, such a polynucleotide thus obtained would be useful as a probe since it would be expected to hybridize to its respective basic polynucleotide to which it has at least 95% polynucleotide sequence identity.

Additionally, applicant urges that such polynucleotides are described by the present specification as useful polynucleotides. Polynucleotides which are at least 95% identical to the polynucleotide sequences admitted by the Examiner to be useful also would be useful as probes for isolating the polynucleotides which the Examiner has admitted are useful and would be expected to hybridize to one of them under stringent conditions. Such use as probes is taught by the present specification (for example, pages 9 to 11 of the specification) wherein it is described that such may be useful as probes to recover the polynucleotide according to SEQ ID NO:1, or as a diagnostic probe or as a PCR primer, for example.

A single utility for a polynucleotide is all that is necessary to meet the requirements of 35 U.S.C. §112. Polynucleotides having at least 95% identity to the sequence referenced by the Examiner are preferred probes for isolating the sequence pointed to by the Examiner. Biological utility similar to that of the polynucleotide referred to by the Examiner is not necessary for such a patentable utility. Therefore, regardless of the outcome of a biological assay for similar biological results, the polynucleotides having at least 95 % identity to the polynucleotide sequence referred to by the Examiner would be useful probes.

Accordingly, with regard to polynucleotides having at least 95% identity to a respective polynucleotide encoding the polypeptide of SEQ ID NO:2, the rejection under 35 U.S.C. §112, first paragraph, of the present claims should be withdrawn since

the present claims which recite polynucleotides having 95% identity to the polynucleotides (or their redundant equivalents) recited by the Examiner are clearly supported by the specification.

The polypeptide production process claims were also rejected under 35 U.S.C. §112, first paragraph, as lacking enablement with regard to polypeptides encoded by the polynucleotides having at least 95% sequence identity to a polynucleotide encoding a polypeptide according to SEQ ID NO:2, or encoded by their complements. Such rejection is believed to be deemed moot for the reasons set forth in the above traversal of the utility for the polypeptides resulting from complements to a polynucleotide encoding the amino acid sequence according to SEQ ID NO:2. Regardless of any other utility (such as biological activity) such polypeptides would be useful for making antibodies such as monoclonal antibodies for detecting the presence of the respective polypeptide in a sample.

Therefore, one of ordinary skill in the art, in view of the state of the art would appreciate that such antibodies would be useful in the production of host cells comprising the respective polynucleotide (with a polynucleotide sequence other than SEQ ID NO:1), for example. Such antibodies to the polypeptide (which may be biologically active or inactive, with respect to the biological activity of the polypeptide according to SEQ ID NO:2) may be utilized to determine if a construct comprising the respective polynucleotide has been successfully inserted into a host cell.

The host cell having the insert can then be cultivated and a polynucleotide probe can be utilized to isolate the multiplied construct polynucleotide from the host cells after destruction of the cell walls of the host cells, for example.

Thus, with regard to the utility of polypeptides produced by the process claims that are presently before the Examiner, such is believed to be clear in view of the above amendment and the original specification, particularly in view of the state of the art. Thus, there is no question that the starting materials for the process for producing the polypeptides of at least the same scope of the polypeptide production claims are fully supported by the specification as indicated above. The only issue, therefore, was the issue of utility for the polypeptides produced and it is satisfied by the description in the specification of how to use such polypeptides to produce useful monoclonal antibodies.

For the above reasons, all of the presently claimed polynucleotides and polypeptides are fully supported as useful compositions with regard to the requirements of 35 U.S.C. §112, first paragraph. Accordingly, this adequately rebutted ground of rejection should be withdrawn.

For the above stated reasons, in view of the above amendments, this case is believed to now be in condition for allowance. An early notice to that effect is urged.

The Examiner is invited to call the undersigned at the below number if any further action by applicant would expedite the examination of this application.

FIRST CLASS MAIL CERTIFICATE

Deposit date: August 13, 1997

I hereby certify that this paper and the attachments hereto are being deposited with the U.S. Postal Service "First Class Mail" service under 37 CFR 1.10 on the date indicated above addressed to:

Box Amendment Response - Fee Due
Assistant Commissioner for Patents
Washington, DC 20231

8/13/97

J.G. Mullins, Esq. **Date**

N:\H\HGS-AMD.458

Respectfully submitted,

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